



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0360]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Safety Communication Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0341. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850,

PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Safety Communication (formerly known as Public Health Notification) Readership Survey

--(OMB Control Number 0910-0341)--(Extension)

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) gives FDA authority to disseminate information concerning suspected or imminent danger to public health by any regulated product. Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) also authorizes FDA to conduct research relating to health information.

FDA's Center for Devices and Radiological Health (CDRH) carries out FDA's regulatory responsibilities regarding medical devices and radiological products. CDRH must be able to effectively communicate risk to health care practitioners, patients, caregivers, and consumers when there is a real or suspected threat to the public's health. CDRH uses safety communications to transmit information concerning these risks to user communities. Safety communications are released and available to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers, as well as patients, caregivers, consumers, and patient advocacy groups. Through a process for identifying and addressing postmarket safety issues related to regulated products, CDRH determines when to release safety communications.

FDA seeks to evaluate the clarity, timeliness, and impact of safety communications by surveying a sample of recipients to determine the impact of safety communications on the

knowledge of the recipients. Understanding how the target audiences view these publications will aid in determining what, if any, changes should be considered in their content, format, and method of dissemination. The collection of this data is an important step in determining how well CDRH is communicating risk. The results from this survey will emphasize the quality of the safety communications and customer satisfaction. This will enable us to better serve the public by improving the effectiveness of safety communications.

We updated the title of the survey from "FDA Public Health Notification Readership Survey" to "FDA Safety Communication Readership Survey" to accurately reflect the information that is being collected.

In the Federal Register of February 10, 2014 (79 FR 7677), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Public Health Notification Readership Survey	300	3	900	0.17	153

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the Safety Communication program, it is estimated that an average of 3 collections will be conducted per year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey.

Dated: May 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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